COLORADO
Department of Health Care Policy & Financing

MINUTES OF THE MEETING OF THE COLORADO MEDICAID P&T COMMITTEE

Department of Healthcare Policy and Financing
303 E. 17th Ave, 7th Floor Conference Room

April 5, 2016

1. Call to Order

A quorum being present, L. Parry officially called the meeting to order at 13:10.

2. Roll Call

Board introductions were made. There were sufficient members for a quorum with eight members participating and three members excused.

A. Members Present

Lynn Parry, MD
Deanna Tolman, FNP
James Feinstein, MD
Steven Russell, MD
Kimberley Jackson, DO
Roy J. Durbin Jr., MD
Andrew Davis, PharmD, MBA
Gwen Black, PharmD
Michelle Beozzo, PharmD

B. Members Excused

Leslie Moldauer, MD, MBA
Patricia Lanius RPh
Jennifer Hyer, MD

C. Staff Present

Robert Lodge, PharmD
Nila Mahyari, PharmD
Sara Haynes

3. Announcements

None

4. Approval of Minutes

L. Parry asked for approval of the minutes from the January 5, 2016 meeting. J. Feinstein seconded the motion. The minutes were approved with no audible dissent.

5. Department Updates

R. Lodge gave an update on the PDL changes for the following:

- Alzheimer's agents
- Atypical Antipsychotics
- Growth Hormones
- Leukotriene Modifiers
- MS Agents
- Intranasal corticosteroids
- Insulin
- Ophthalmic allergy products
- Sedative/Hypnotics
- Statins and Statin combinations

R. Lodge reported that PDL went into effect 4/1/16.

R. Lodge gave updates about the prior authorization helpdesk call statistics. The prior authorization numbers from the previous month were about the same as usual. This being about 86% approvals and 14% denials. The average hold time is 35 seconds. A. Davis asked if abandonment rates were tracked. There was some discussion as to the customer call center response times. R. Lodge reported that this information was specifically with the pharmacy technicians and that the Department does not have the metrics for the call center. There was discussion from the committee that abandonment rates would be helpful data.

6. Rules

L. Parry presented guidelines and rules for manufacturer and public presentations. Oral presentations will be restricted to products that are being reviewed for PDL

status. Presentations must be limited to a maximum of three minutes per representative per drug product. Representatives will be called to present in the order in which they signed in by drug class. Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted. Presentations should follow the one page summary that was submitted to the Department. The audience will be considered a reference tool for the committee. The committee will discuss topics and audience participation will be allowed if P&T members ask for clarification. The Department disseminated recently received public comments to the committee members.

Factual Inaccuracy:

During a Committee meeting, if a stakeholder believes that a factual inaccuracy has been stated by a Committee member, the stakeholder may hand a note to the Department representative or Committee Chair or Vice Chair. The stakeholder must provide the factual inaccuracy or a summary of the inaccuracy on the note. The Department representative will forward any comment to the Chair or Vice Chair. The Committee Chair/Vice Chair will then determine if there is need to publicly hear the inaccuracy prior to moving forward with motions and discussion. The Chair/Vice Chair will state the purported factual inaccuracy and will ask the Committee if they want to hear testimony regarding the factual inaccuracy. When providing testimony, the stakeholder must provide evidence to support the claim of inaccuracy and cannot provide opinions on the drug class being considered.

A. DRUG CLASSES FOR REVIEW

1. L. Parry moved to discuss Antihistamine and combinations. With no speakers present R. Lodge gave FDA updates, utilization information, and current preferred products. K. Jackson made the motion to make available at least two different antihistamine agents with different mechanisms. K. Jackson discussed the the need for different options available to Medicaid clients. A. Davis asked for clarification between agents and generations. A. Davis reporteded they were H1s and was not sure how there could be different mechanisms. K. Jackson made the motion to keep the prior motion to make available at least two different antihistamine agents. J. Feinstein seconded. The motion passed with no audible dissent. K. Jackson made the motion that because single agents are safer than combination products with respect to drug-drug interactions at least one single agent be preferred. D. Tolman seconded the motion. The motion passed with no audible dissent. No further motions.

2. L. Parry moved to discuss Angiotensin Receptor Blockers and combinations. R. Lodge gave FDA updates, utilization information, and current preferred products. D. Tolman made the motion to consider at least one ARB with renal

protectin data in diabetes and one ARB with heart failure data in this class. K. Jackson seconded. R. Durbin discussed that by defination, this class of drugs is renial protection and there will be no additional research on it. L. Parry there are drugs that have completed additional data. R. Durbin disagreed. A. Davis clarified how data is defined. R. Lodge clarified the Department definition. D. Tolman chose not to amend wording of motion. L. Parry clarrified the wording of motion to support options for Medicaid members and providers. The motion passed with no audible dissent.

3. L. Parry moved to discuss Renin Inhibitors and combinations. With no speakers being present. R. Lodge gave FDA updates, utilization information, and current preferred products. K. Jackson made the motion that due to safety concerns we do not need a preferred product in this class. G. Black seconded. The motion passed with no audible dissent.

4. L. Parry moved to discuss Fibromyalgia agents. T. Hartman from Pfizer wanted to ask the board to continue to make Pregabalin or Lyrica available to Medicaid population and have an option that is a non-opioid option for pain management. R. Lodge gave FDA updates, utilization information, and current preferred products. L. Parry questioned the previous motion made due to limited studies. R. Lodge clarifies the statement of "that no one product is proven more effective than others." Previous motion not remade. K. Jackson proposed new motion that at least two agents with different mechanisms of action be available. R. Durbin seconded. L. Parry stated that it was equally effective to make the motion that at least one preferred agent is not a controlled substance. There was discussion as to the difference of the motions. A. Davis referenced that a new FDA approved drug could be released. K. Jackson made the motion that at least two agents with different mechanisms of action be available. A. Davis seconded. The motion passed with no audible dissent. A. Davis made the motion that at least one preferred agent in the fibromyalgia class is not a controlled substance. D. Tolman seconded. R. Durban asked the defination of a controlled substance. A. Davis reported DEA classification 2-5. The motion passed with no audible dissent.

5. L. Parry moved to discuss Long Acting Oral Opioids. R. Shah from Purdue spoke about opioids with abuse deterrent properties specifically Burtrans, Hysingla, and OxyContin. L. Parry asked for clarification of Burtrans dosages. G. Smeshesh from Pfizer spoke about Embeda and it's abuse deterrent properties. D. Hermain from Pfizer spoke about Embeda and it's benefits to to patients for long term pain management as well as it's abuse deterrents. A. Reish DO spoke about Buprenorphine and Nucynta in the form of Butrans. Buprenorphine is only schedule 3. A. Reish spoke about the abuse deterrents and beneficial properties. L. Parry asked about Suboxone a special license waiver. R. Durbin asked why it wasn't on the list. K. Jackson answered that

it does not have an FDA indication for chronic pain which is why it is not on the list. K. Jackson asked A. Reish to explain safety and efficacy. R. Lodge gave FDA updates, utilization information, and current preferred products. L. Parry read a comment from previous meeting that said there is no evidence that definitely supports a difference between short and long acting opioids. K. Jackson did not agree with wording and wanted to discuss. L. Parry stated that in regards to literature on safety and efficacy only, there is no difference. K. Jackson felt that abuse potential. D. Tolman, A. Davis, and R. Dubin disagreed with the statement and felt that is what a DUR schedule does. D. Tolman requested that define difference. L. Parry provided explanation. K. Jackson discussed current restrictions. L. Parry discussed legacy cases. K. Jackson discussed medication accessibility. R. Lodge clarified medication accessibility and how the DUR examines medication and population. R. Durbin commented that he felt there is some controversy to the statement. N. Mahyari stated the Medicaid policy and examining individual cases. D. Tolman and K. Jackson commented about opioid restrictions and patients affected. D. Tolman asked for A. Reish's assistance on how to word motion. D. Tolman made motion that they would like at least one class 3 long acting abuse deterrent opioid included. R. Durbin seconded. 6 I's, 1 nay, and 1 abstain. Motion passed. G. Black made a motion to add one product that has long acting, full agonist that has abuse deterrent properties. K. Jackson seconded. The motion passed with no audible dissent. There was discussion among committee members as to how to assist members unable to orally take medication. K. Jackson made a motion that at least one pure long acting agonist opioid available for people who have difficulty swollening. D. Tolman seconded. The motion passed with no audible dissent. D. Tolman made the motion that the very narrow therapeutic window and safety be considered making a long acting medication preferred. R. Durbin seconded. The motion passed with no audible dissent. K. Jackson made a motion that at least one long acting opioid agent be available in transdermal form. D. Tolman seconded. The motion passed with no audible dissent. K. Jackson made the motion to include at least two long acting oral opioids in addition to methadone as preferred. M. Beozzo seconded. The motion passed with no audible dissent. D. Tolman made a motion to make one long acting opioid that is indicated for Diabetic Peripheral Neuropathy preferred. K. Jackson seconded motion. The motion passed with no audible dissent.

6. L. Parry moved to discuss Inhaled Anticholinergics and combinations. S. Painter from Boehinger Ingelhiem spoke Stiolto. R. Lodge gave FDA updates, utilization information, and current preferred products. J. Feinstein made the motion that pediatric indications should be considered as well as dosage forms. S. Russell seconded. Some discussion of current PDL status. The motion passed with no audible dissent. There was discuss regarding prior motion that based on similar safety and efficacy we cannot recommend one

product over another. The committee elected to put this motion on hold to collect more data. K. Jackson made the motion that at least one short acting and one long acting nebulizer solution be preferred. A. Davis seconded. The motion passed with no audible dissent. K. Jackson made the motion that at least one short acting and one long acting rapid delivery device product be preferred (no nebulizer required). D. Tolman seconded. The motion passed with no audible dissent. D. Tolman referenced letters submitted. D. Tolman made a motion that at least one long acting anticholinergic and LABA combination product be preferred. Committee discussed safety and requested data. R. Lodge and N. Mahyari discussed DUR review and timeline. D. Tolman withdrew motion.

K. Jackson excused self from meeting.

7. L. Parry moved to discuss inhaled beta 2 agonists. With no speakers present R. Lodge gave FDA updates, utilization information, and current preferred products. R. Durbin wanted to comment that he has had a lot of success with Respiclick. B. Welling gave further explanation on the product. R. Durbin made the motion that due to increased compliance efficacy a breath actuated inhaler should be considered for the preferred list. D. Tolman seconded. 7 "I"s, 1 abstain. Motion passed. J. Feinstein made the motion to continue the current policy of allowing one inhaler with a dose counter and one inhaled solution to be preferred. S. Russell seconded. The motion passed with no audible dissent.

8. L. Parry moved to discuss Inhaled Beta 2 agonists (long acting). No presenters. R. Lodge gave FDA updates, utilization information, and current preferred products. D. Tolman made the motion that all single entity LABAs should be considered non-preferred and require a prior authorization due to potential safety concerns. G. Black seconded. The motion passed with no audible dissent.

9. L. Parry moved to discuss Inhaled corticosteroids and combinations. A. Martens from Meda spoke about Aerospan. B. Raleigh NP from Children's Hospital spoke regarding choices for devices and combinations. She also discussed denial of some prescriptions due dose. R. Lodge reported that he will look into why some dosages are denied. D. Tolman suggusted a label stating that the smaller dose is not covered and to please try the 13 gram. R. Lodge gave FDA updates, utilization information, and current preferred products. J. Feinstein made the motion to include at least one single agent product from each delivery method (MDI, DPI, and nebule). M. Beozzo seconded. The motion passed with no audible dissent. D. Tolman make the motion to prefer one product with pregnancy category B. M. Beozzo seconded. There was discussion as to why different sources classify in two

different categories. B. Hoss clarified the issue. The motion passed with no audible dissent. D. Tolman made the motion for the combination products to include at least one MDI and at least one DPI with a dose counter preferred. M. Beozzo seconded. The motion passed with no audible dissent. Committee discussed the need for dose counters. J. Feinstein made the motion that all preferred products (DPI and MDI) have a dose counter. D. Tolman seconded. The motion passed with no audible dissent.

10. L. Parry moved to discuss skeletal muscle relaxants. With no speakers present R. Lodge gave FDA updates, utilization information, and current preferred products. L. Parry made the motion to include at least one agent to treat spasticity as preferred. D. Tolman seconded. The motion passed with no audible dissent. D. Tolman made the motion to include at least one skeletal muscle relaxant as preferred. G. Black seconded. The motion passed with no audible dissent. M. Beozzo made the motion that Soma has a high addiction profile and should not be preferred because of safety reasons. D. Tolman seconded. The motion passed with no audible dissent.

    A. Davis excused self from meeting.

11. L. Parry moved to discuss testosterone products. With no speakers being present R. Lodge gave FDA updates, utilization, and current preferred products. D. Tolman spoke on testosterone/cardiologic study data. D. Tolman made a motion that due to safety and suspected overutilization we recommend all products require a prior authorization. J. Feinstein seconded. Motion passed with no audible dissent.

12. L. Parry moved to discuss topical immunomodulators. With no speakers present R. Lodge gave FDA updates, utilization information, and current preferred products. R. Lodge reported the Department's stance. J. Feinstein presented pediatric perspective. The committee discussed recommendation to the DUR board that these products always be used as second line to topical steroids.

7. The meeting was adjourned at 1737.

By: Lynn Parry

Lynn Parry, MD, Chair

Date: 7/5/16

Reasonable accommodations will be provided upon request for persons with disabilities. Please notify the Committee Coordinator at 303- 866-3982 or Kelli.Metz@state.co.us or the 504/ADA Coordinator hcpf504ada@state.co.us at least one week prior to the meeting.